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(54) Title: VERTEBRAL BODY REPLACEMENT DEVICE

(57) Abstract: The invention provides a spinal part replacement, a system including a spinal part replacement and instrument, distractor instrument and method of surgery which addresses problems with existing spinal part replacement designs. In particular the invention provides a spinal part replacement formed of a first component, second component and a body, the first and second components being introduced to the location of the spinal part to be replaced separately from the body. It is particularly beneficial that this be achieved by mounting first and second components on a distractor instrument, inserting the first and second components into the space in a reduced profile form and then expanding the profile within the space, the first and second components serving to distract the vertebrae and then forming part of the spinal part replacement once distraction has been completed, by means of an insertion of a body between them.

VERTEBRAL BODY REPLACEMENT DEVICE

The present invention is concerned with a vertebral body and/or vertebral disc replacement device, which may be thought of as a spinal implant, prosthesis or replacement. The invention includes spinal implants, spinal implant systems, methods of implanting and accompanying instruments, particularly, but not exclusively in relation to an anterior spinal implant system for vertebral body replacement.

The system presented is, particularly, an intervertebral assembly, for insertion of a cage or other vertebral body replacement. The system, particularly, comprises two vertebral end plates connected to a special distraction device, and a vertebral body replacement, for example mesh titanium ceramic or any other material. The system is also applicable to vertebral disc replacement.

The removal of a vertebral body, particularly anteriorly, is required in a variety of spinal disorders, such as primary or secondary tumors, infections or trauma of the spinal column. These pathologies may require replacement of the damaged vertebra for decompression and stabilization of the spinal column by means of metal or ceramic intervertebral implant, such as a cage or other vertebral replacement.

Removal of a vertebral body and insertion of an implant, is technically complicated. The operation is carried out in a complex anatomical area and it requires the creation of a space along the spinal column as part of the decompression process. Stabilizing of the spine is achieved by insertion of the vertebral body replacement after distraction of the adjacent vertebrae.

Particular issues arise with the need to distract the adjacent vertebrae to a sufficient extent to allow the insertion of present implant designs. To insert the implants the level of distraction often needs to be significantly greater than the final implant size, so increasing the level of disturbance to the spine and surrounding tissue. There are also issues with the way in which the vertebrae are distracted as there is either a need for tool access to the space between the vertebrae, so increasing the extent of distraction needed, or a need to generate firm anchors in the adjacent vertebrae for the distraction process, through screws for instance, which again increases the size of the disturbance and necessitates damage to the adjacent vertebrae.

The innovation proposed substantially simplifies the procedure of adjustment, distraction and insertion of a vertebral body implantor prosthesis into the vertebral column, resulting in a faster and safer outcome, without increasing the cost of the implant and in

addition reducing trauma to surrounding tissue. The invention has amongst its aims the use of an implant in which a part of the implant previously assists in the distraction process, and in particular forms part of the distraction tool. The main advantage of this innovation lies in the use of the end plate as integrated part of the distractor and than changing its role to be used as integral part of the implant, serving as base and interfaces between the implant (cage or other) and the vertebrae.

According to a first aspect of the invention we provide a spinal part replacement, the replacement including a first component, a second component and a body, at least a part of the body being provided between the first component and the second component in the assembled form, the first and second components being introduced to the location of the spinal part to be replaced separately from the body.

Preferably the first component engages one end of the body and, the second component engages the other end of the body.

According to a second aspect of the inventionwe provide a spinal part replacement, the replacement including a first component a second component and a body, the first component engaging one end of the body, the second component engaging the other end of the body.

The first and second aspects of the invention may include one or more of the following features, options or possibilties.

Preferably the spinal part being replaced is a vertebra or a plurality of vertebrae. The discs adjacent each of the vertebrae are preferably replaced together with the replacement of the vertebrae. Preferably the spinal part replacement is rigid in such a case. The spinal part being replaced may be a disc. Preferably the spinal part replacement is at least in part rigid, particularly the parts of components or components themselves which contact the adjacent parts of the spine to those replaced. In such a case the spinal replacement may include one or more non-rigid parts, for instance the body or a part thereof.

Preferably the first component includes one or more planar faces. Both opposing faces of the first component may be planar. The first component may be a planar element. The first component may be a disc, preferably of circular cross-section.

The first component may include one or more apertures. The apertures may be provided to encourage bone growth. The apertures may be provided to assist in fixing the first component and body together. The apertures may be provided to assist in fixing the first component to the adjacent vertebra. The apertures may be formed in providing parts to fix the first component and body together. The apertures may be formed in providing parts to fix the first component to the adjacent vertebra. A regular and preferably symetrical pattern of apertures may be provided.

One or more spikes and/or points and/or protrusions may be provided on one or both faces of the first component. Preferably one or more spikes and/or points and/or protrusions are provided on one face of the first component to assist the engagement between the first component and the adjacent vertebra in use. The spikes and/or points and/or protrusions may, at least in part, enter the vertebra in use. The spikes and/or points and/or protrusions preferably project from the first component to an equivalent extent in each case. Preferably at least four such spikes and/or points and/or protrusions are provided. Preferably the spikes and/or points and/or protrusions are provided fully inside the perimeter profile of the first component. The spikes and/or points and/or protrusions may be formed by deforming a part of the first component out of the plane of the first component. The deformation may leave an aperture for each spike and/or point and/or protrusion formed. The spikes and/or points and/or protrusions may extend perpendicular to the plane of the first component. The spikes and/or points and/or protrusions may taper away from the first component.

Preferably one or more spikes and/or points and/or protrusions and/or rings are provided on the face of the first component with which the body engages in use. The spikes and/or points and/or protrusions and/or rings are preferably provided in a configuration which matches the exterior profile of the body. Preferably the spikes and/or points and/or protrusions and/or rings are provided outside the profile of the body in use. One or more spikes and/or points and/or protrusions and/or rings may be provided within the profile of the body in use. One or more of the spikes and/or points and/or protrusions may have a different extent of projection from the first component than the other spikes and/or points and/or protrusions. A part of one or more of the spikes and/or points and/or protrusions and/or rings may be missing compared with the others form. Preferably one or more of the spikes and/or points and/or protrusions have a lesser extent of projection than one or more gaps in the body. The one or more spikes and/or points and/or protrusions may have a profile which is less than one or more gaps in the body. One or more rings

may be provide with one or more gaps. Preferably the lesser extent and/or profile and/or gaps allow the passage of the body in certain orientations, particularly over the surface of the first and/or second component.

The one or more spikes and/or points and/or protrusions and/or rings may be provided by deforming a part of the first component prior to insertion into the location. The deformation may occur at the site of the procedure or may occur during manufacture.

The first component may be provided with one or more engagement locations. Preferably an instrument engages with the engagement locations during introduction of the first component to the location. The engagement locations may be provided by apertures in the first component. Preferably the engagement locations are provided by recesses in the perimeter of the first component. The recesses may be generally rectangular. Preferably the engagement locations extend throught the first component.

The first component may be provided with an aperture, preferably in its centre, for receiving a screw or other releasable fastener. Preferably the screw or other releasable fastener is introduced through the aperture into the vertebra adjacent the first component.

Preferably the first component has a greater extent, for instance perpendicular to the axis of the body, in one or more directions than the body. Preferably the extent is greater in all radial directions. Preferably the extent is equal in all radial directions.

Preferably the first component is rigid. The first component may be of metal..

The second component may have any of the features set out above for the first component. Preferably the second component is identical to the first.

Preferably equivalent first and second components are marked with the same distinctive marking, such as colour. The first and second component may be of the same colour as each other throughout.

The first component and/or the second component and/or the body may be coated in or provided with bone growth promoting material. The bone growth promoting material may be or include hydroxyapetite and/or bone growth factor.

Preferably the body is of cylindrical cross-section. Preferably the body has a first end which engages with the body, ideally due to a match between the profile of a least a part of the body and at least a part of the first component. Preferably at least a part of the body has a generally planar configuration at one end and ideally at both. Preferably the body has a second end which engages with the body, preferbaly due to a match between the profile of at least a part of the body and the second component. Preferably one, and ideally both of the ends of the body have one or more parts on a plane. The one or more

parts on the plan may be the ends of spikes and/or points and/or protrusions and/or rings, and particualrly the end surfaces of such parts.

The body may be a cage. The body may be provided with one or more apertures in its side. The body may have apertures all over its side. The body may have one or more apertures to promote bone growth. The body may be formed of mesh. The body may be formed of metal, such as titanium or titanium incorporating metals. The apertures in the side wall of the body may be generally diamond shaped. The side of the end of the body may have one or more partial diamond shaped gaps, with an open side. The ends of the body may be open.

In an alternative embodiment the body may be formed of two elements whose position relative to one another can be varied. Preferably the variation is obtained by rotation of one or both elements relative to the other. A screw thread engagement between the two elements may be provided. The two elements may be cylinders. The cylinders may be open or closed at the ends. One or more apertures may be provided in the side of the body.

The body may be provided with, and is preferrably packed with, bone growth promoting materials and/or fragments of bone.

One or more parts of the body may cooperate with one or more parts of the first component and/or second component to resist, and ideally prevent, separation of the first component from the body and/or second component from the body. Ideally relative movement is prevented. Separation and/or movement may be resisted by an engagement between a part of the first component and/or second component and the body. The engagement may occur within the profile of the body and/or outside the profile of the body. Preferably once the body is in place relative to the first component and/or second component a change is effected to provide the engagement. The change may be a change in orientation of the body, for instance by rotation. The change may be a change in configuration of one or more parts of the first and/or second component and/or body, for instance by the deformation of a part of the first component and/or second component and/or body. The change may be achieved by introducing a part to the first component and/or second component and/or body, for instance a releasable fastener. The change may be effected by the application of a magnetic or electric force between the body and the first and/or second component.

Preferably the body can be slid into position over a surface of the first and/or second components. Preferably the body can slid into position in one orientation of the

body relative to the first component and/or the second component. Preferably the body cannot slid relative to the first component and/or second component in one or more other orientations. Preferably the orientation is changed from a one orientation to an other orientation once the body has been positioned relative to the first component and/or the second component. A retaining element may be provided or introduced to prevent the body returning to a one orientation from the an other orientation after positioning.

Preferably the whole of the body is provided between the first component and the second component. Preferably an end of the body engages the first component, but ideally without passing into or through it. Preferably another end of the body engages the second component, ideally without passing into or through it.

Preferably the body is rigid. The body may be of metal. The body may include one or more flexible or deformable parts, particualrly in the case of a spinal disc replacement where mobility is still required.

Preferably the first and second component are introduced to the location together. Preferably the body is introduced to the location after the introduction of the first and second components. Preferably the body is slid between the first and second components in the location.

According to a third aspect of the invention we provide a system for use in providing a spinal part replacement, the system including one or more spinal part replacements, a spinal replacement including a first component, a second component and a body, at least a part of the body being provided between the first component and the second component in the assembled form, the first and second components being introduced to the location of the spinal part to be replaced separately from the body, the system further providing a distractor instrument.

Preferably the first component engages one end of the body and, the second component engages the other end of the body.

According to a fourth aspect of the invention we provide a system for use in providing a spinal part replacement, the system including one or more spinal part replacements, a spinal part replacement including a first component a second component and a body, the first component engaging one end of the body, the second component engaging the other end of the body, the system further providing a distractor instrument.

The third and fourth aspects of the invention may include one or more of the following features, options or possibilties, aswell as any of the features, options or possibilities set out above in relation to the first and/or second aspects of the invention.

Preferably the distractor instrument includes an end inserted in the location and an end held by a user.

Preferably the location end of the instrument includes a first engagement location between the instrument and a first component. Preferably the location end of the instrument includes a second engagement location between the instrument and the second component. The engagement location may be provided, in one or both cases, on a projection from the body of the instrument. The projection may be in the form of two elements with a gap between them. Preferably the gap is open ended at the location end. The gap is preferably configure to accommodate the first and/or second components, ideally between the elements.

Preferably the location end of the instrument is provided with two sets of engagement locations and/or projections and/or elements, the two sets being mirror images of one another.

The engagement location may include a plurality of points of engagement.

Preferably points of engagement are provided which engage with locations on opposing sides of the first and/or second components. Preferbaly the locations are diametrically opposed to one another, in terms of the first and/or second component. The engagement location may include a first part or point which engages a surface of the first component or second component. Preferably such a first part or point engages with a planar surface of the first or second component. Preferably the first part or point engages with the same face of the first or second component as is engaged by the body. Preferably the first part or point of the engagement location for the first component faces away from the first part or point of the engagement location for the second component. Preferably two first parts or points are provided for each of the first component and the second component. The first part or points for the first and second components may be provided by planar surfaces on the elements, ideally with the planes of the surfaces being parallel to one another.

Preferably points of engagement, ideally in addition to the points of engagement of the previous paragraph, are provided which engage with the side of the first component and/or second component. These side points of engagement may engage with one or more

recesses in the first component and/or second component. Preferably the side points are positioned adjacent to the other points. The side points may be formed by one or more projections of lugs. The projections or lugs may have a greater extent of projection than the thickness of the first or second component. The projections or lugs may project fromt the surface of the elements which define the gap. Preferably at least two side points are provided for the first and/or second components. Preferably in opposition to one another.

Preferably the separation between the side points is preferably less than the extent, ideally diameter, of the first and/or second components. The separation may be variable. Preferably the separation of the face points is less than the extent, ideally diameter, of the first and/or second components. The separation may be variable.

The means for varying the extent of distraction of the instrument may be provided on or at the user end of the instrument. The means for varying the extent of distraction may comprise a mechanical system, electrical system, pneumatic system or hydraulic system. The extent of distraction may be varied by rotation of a handle, for instance positioned on the user end of the instrument. The extent may be varied by varying the separation of two opposing points in a parallelegram, the other two opposing points being mounted on the body of the instrument.

Preferably the instrument is form of a body in tow parts, the two parts being linked by the mechanism for varying the extent of distraction.

The instrument may provide a readable measure of the extent of distraction. Ideally the measure is of the distance between the two opposing faces of the first and second components. Preferably the measure indicates the length of the body which needs to be provided.

The extent of distraction/separation of the engament locations with the first and second components may be varied between a first state and a second state. Preferably the first state represents a lower extent of distraction/separation than the second state. An intermediate state may be provided. Preferably the location end of the instrument is inserted into the location end in the first state. Preferably the transition to the intermediate state brings the first and second components into contact with the vertebrae. Preferably the transition to the second state causes distraction of the vertebrae.

According to a fifth aspect of the invention we provide a distractor instrument, the distractor instrument having an end inserted in a surgical location and an end held by a user, the inserted end having one or more engagement locations to support a first

component and one or more engagement locations to support a second component, the first and second components not being a part of the instrument, the separation of the engagement locations for the first component and engagement locations for the second component being variable.

The distractor instrument may include any of the features, options or possibilities set out elsewhere in this document, including those set out above in relation to the third and fourth aspects of the invention.

In particular the instrument provides engagement locations for a first component and for a second component, the first and second components being part of the spinal part replacement.

According to a sixth aspect of the invention we provide a method of providing a spinal part replacement, the method including:-

removing the part of the spine to be replaced by means of an incision;

providing a spinal part replacement including a first component, second component and body;

mounting the first and second components on a distraction instrument;

inserting the first and second components and a part of the distraction instrument into the space left by the part of the spine which has been removed;

increasing the spacing between the first component and the part of the distraction instrument the first component is mounted upon relative to and the second component and the part of the distraction instrument the second component is mounted upon, the first component contacting one vertebra, the second component contacting an adjacent vertebra;

increasing the spacing between the first component and the second component further, the first and second components increasing the spacing between the one vertebra and the adjacent vertebra;

inserting the body between the first component and the second component;

reducing the separation between the part of the distraction instrument the first component was mounted on and the part of the distraction instrument the second component was mounted upon;

removing the distraction instrument from the incision.

The sixth aspect of the invention may include any of the features, options or possibilities set out elsewhere in this document, including those set out above in relation to the first, second, third, fourth and fifth aspects of the invention.

The part of the spine may be a vertebrae or a plurality of vertebrae. The part of the spine may be a disc. The part of the spine may be the cylindrical body portion of one or more vertebrae.

Preferably the part of the spine is removed anteriorly. The part of the spine may be removed using a formal antero-lateral exposure of the spinal column. The method may involve a corpectomy.

The opposing surfaces of the remaining vertebrae may be cleaned, for instance up to the burr and / or bleeding subchondrial bones. Templating of the exposed surfaces of the remaining vertebrae may be performed.

Preferably the first component and / or second component and / or body are provided as per the disclosures elsewhere in this document.

The first component may be mounted on the distraction instrument using one or more engagement locations. Engagement locations in the form of supporting surfaces on the instrument may be provided. The supporting surfaces may be provided at or near the ends of elements projecting from the end of the instrument to be inserted into the incision. The second component may be mounted on the distraction instrument using one or more engagement locations. Engagement locations in the form of supporting surfaces on the instrument may be provided. The supporting surfaces may be provided at or near the ends of elements projecting from the end of the instrument to be inserted into the incision. The first and / or second component may be mounted on the distraction instrument using one or more lugs and / or projections.

Preferably the first and second components and the part of the distraction instrument are inserted into the space left by the part of the spine which has been removed with the instrument in a first state. Preferably the profile occupied by the part of the instrument and the first and second components is lower than the profile of the space in the first state. Preferably the part of the instrument, first component and second component occupy less space in the first state than the space left by the part of the spine which has been removed. Preferably the extent of distraction is variable between the first state and second state. Preferably the first state represents a lower extent of distraction / separation from the second state. An intermediate stage may be provided. Preferably the transition

from the first state to the intermediate state brings the first and second components into contact with their opposing vertebral surfaces. The transition from the first state to the intermediate state may cause spikes and / or points and / or protrusion present on the first or second component to engage with the vertebrae, and ideally enter the vertebrae. This process may be completed during the transition from first to intermediate state, or may continue during the transition from intermediate to second state. Preferably the transition from intermediate to second state causes the vertebrae to be moved apart. Preferably the transition from intermediate to second state causes the first and second components to move apart. Preferably the vertebrae are in the desired, normal position of use in the second state. Preferably no over-distraction is present in the second state.

Preferably the transition from first to intermediate state and / or intermediate state to second state involves the first and second components remaining parallel to one another throughout and / or involves the opposing vertebral surfaces of the remaining vertebrae remaining parallel throughout.

Preferably a measurement of the body required is taken in the second state. The measurement may be taken by reading the output from a measurement device provided as a part of the instrument and / or as an addition thereto. Preferably the body is provided at the desired length. The body may be provided at the desired length by cutting and / or other working.

Preferably the body is inserted between the first and second components by sliding. The body may be inserted between one or more pairs of projections on the instrument before insertion between the first and second components. Sliding contact between one or both ends of the body and the first and second components may occur.

After the insertion of the body between the first and second components, the body and first and second components may be fixed in position relative to one another. Fixing may occur due to movement of the body relative to the first and second components and / or due to movement of a part of the body and / or of the first component and / or of the second component into a retaining position. An element may be introduced to the body and / or the first component and / or the second component to provide the fixing.

Preferably the separation between the part of the distraction instrument of the first component was mounted on and the part of the distraction instrument the second component was mounted on is achieved by reversing the transition from second state towards the first state or intermediate state. The transition may be reversed as far as the intermediate state and / or reversed as far as the transition to the first state. Preferably the

transition from second to intermediate and / or first state demounts the first and second components from the distraction instrument. The demounting may occur due to the retraction of the lugs or projections on the instrument from the first and second components and / or due to the withdrawal of the part of the instrument which contacts the first and second components into a non-contacting position.

The instrument may be removed from the incision once the engagement locations are demounted from the first and second components. Preferably the transition towards the intermediate and / or first state is advanced to a position where removal of the instrument perpendicular to the axis of the spinal part replacement can occur without contact between the instrument and the spinal part replacement.

Various embodiments of the invention will now be described, by way of example only, and with reference to the accompanying drawings in which:-

Figure 1a is a plan view of a prior art cage style implant;

Figure 1b is a side view of the prior art cage of Figure 1b;

Figure 2 is a perspective view of an implant according to one embodiment of the invention in its deployed form;

Figure 3a is an illustration of a prior art distraction device used for spinal disc replacement in its non-distracted form;

Figure 3b is an illustration of the distraction tool of Figure 3a in a partially distracted form and showing the spinal disc replacement;

Figure 3c is an illustration of the distraction tool of Figures 3a and 3b in a more distracted form with the spinal disc replacement advancing into the disc space;

Figure 4a is an illustration of a distraction tool according to one embodiment of the present invention in partially distracted configuration with end plate discs in place;

Figure 4b is an illustration of the tool of Figure 4a fully distracted and with the vertebral substitute being introduced;

Figure 4c is a detailed illustration of the distraction tool of Figure 4b in its configuration within the vertebral body space with the implant assembled, the vertebrae are omitted for clarity;

Figure 5 illustrates in cross section the positioning of the implant within the spine with the distraction tool still in situ and at its maximum distracted configuration;

Figure 6 illustrates the implant in situ, with the spine omitted for clarity, and with the distraction tool in a reduced distraction configuration to allow the tool withdrawal;

Figure 7 illustrates the prosthesis in situ within the vertebral column after removal of the distraction tool; and

Figure 8 illustrates in detail an embodiment of the present invention in its assembled form with the top end plate disc omitted for clarity.

The present invention relates generally to implants/prosthetic devices for vertebral body replacement to treat patients having corpectomy (vertebral body resection). More particularly, it serves to provide an improved adjustable, easily implantable end plate based prosthesis for insertion and permanent installation intermediate the opposing surfaces of upper and lower vertebrae to replace the removed vertebral body and restore stability and normal vertebrae spacing to the spinal column while facilitating the occurrence of bony integration to fuse the aforesaid vertebrae together.

The main structural support of the human skeleton is the spinal column, a structure which consists of a plurality of vertebrae which are interlinked by flexible joints, spaced apart by intervertebral discs of fibrocartilage and gelatinous nucleus, and held together by ligaments. Each vertebra has a roughly cylindrical body, with wing-like projections, and a bony arch. The arches, which are positioned next to one another, create a tunnel-like space which houses the spinal cord. The anterior cylindrical bodies of the vertebrae, which are spaced apart by intervertebral discs, bear most of the compressive load of the spinal column (between 60 to 80 percent of the total load).

When it occurs, primary and metastatic malignant tumours may case severe pain, some times associated with spinal cord compression (presented as paresis or paraplegia) and vertebral collapse leading to spinal instability. These conditions affect mainly the anterior cylindrical body of the vertebra, which, as mentioned above, is the primary load-carrying part of the spinal column. Other diseases or traumatic damage can cause problems in this area and give rise to the need for vertebral replacement using an implant.

Severe back pain can be among the most relentless and debilitating afflictions occurring to individuals, often making a normal life substantially impossible for victims of such conditions.

The primary objectives of surgical intervention are to preserve the neurological function of the spinal cord and to relieve the intense pain associated with such conditions. It will be appreciated particularly by those skilled in the art that any such surgical intervention will necessarily involve the resection and removal of the vertebral body. The resulting loss of bony support destabilizes the vertebral column, and therefore requires that the excised support material, the vertebrae, be replaced either by a prosthesis, implant or other substitute.

One approach has been to remove the tumourous material, and then fill the space of the resected anterior spine with methylmethacrylate or some other plastic material. This approach has been less than successful, since it is difficult to achieve proper bonding with the bony material of the vertebrae. In addition, such materials often involve an exothermic chemical reaction for the polymerization of the plastic material, which can release a significant amount of heat into the adjacent tissue. In addition, these plastic materials do not exhibit sufficient mechanical strength and stability, even when they are reinforced with metal pins or struts.

Another approach which has been utilized is to use a hollow cylindrical mesh cage which is filled with bone chips or marrow. The bone material may be bone excised from the patient's own fibula or pelvis, or, alternately the allograft material which is an harvested bone from a deceased donor. In the case of a metastatic tumor, bone cement may be used instead of bone chips or marrow. Such a device is illustrated in Figure 1a in plan view and Figure 1b in side view. The cage 100 features a metal mesh 102 with a series of diamond shaped holes 104. The cut off diamonds 106 form a series of points 108 on the top surface 110 and bottom surface 112. The points 108 penetrate the vertebrae surfaces in use.

A spreader is used to separate the vertebrae between which the cylindrical mesh cage is to be inserted. With the distance between the vertebrae maintained by the spreader, the cylindrical mesh cage is inserted into place, with the ends of the cylindrical mesh cage bearing on the opposing end surfaces of the vertebrae. To do this the vertebrae must be distracted by greater than the height of the cage 100. The spreader is then released, so that normal compressive forces of the spine acting on the anterior column may anchor the cylindrical mesh cage 100 in place. In general the end points 108 of the cage 100 push into

the vertebrae slightly and provide a degree of anchorage. Bone cement nay also be applied into the cylindrical mesh cage to maintain the cage 100 in place. It is also possible to incorporate in the implant a ring 114 near the top and bottom of the cage, seen in the plan view, Figure 1a, to increase the load bearing area. The ring 114 is held in place in each case by a series of screws, not shown, inserted into receiving locations 116.

Immediate stabilization of the spine following this procedure does not occur, since it generally takes between three and six months for bony fusion to take place. In addition, if the patient is to be treated by radiation and/or chemotherapy following the surgery, in many cases the radiation and/or chemotherapy will have an adverse affect on the bone graft, preventing it from surviving and fusing the two vertebrae together. In this case, additional surgery will generally be required to establish a satisfactory degree of spinal stability.

Another technique used to stabilize the spine following the removal of the anterior column of a vertebra is the use of a plurality of metal rods which are attached by bolts or screws to the two vertebrae on either side of the removed vertebrae. This technique presents a variety of problems, particularly due to the presence of large localized forces in the areas in which the rods are attached to the vertebrae by the bolts or screws. In addition, some areas of the spine are difficult or impossible to stabilize with this technique due to the presence of sensitive tissue located adjacent to the areas in which the stabilizing rods would be used. The extent of the disturbance caused by the surgical intervention is also greatly increased in such a technique.

It is accordingly the primary objective of the present invention that it provide an improved implant in the form of an end plate prosthesis which may be used following the removal of the anterior column of a vertebra to serve as a metal solid base for the application of any vertebral support, for example mesh titanium cage, ceramic or bone autograft or allograft. The procedure can reestablish spinal stability and maintain proper spacing between the vertebrae located immediately above and below the removed vertebra. It is an objective of the end plate prosthesis of the present invention that it be of a design and physical configuration which may be easily installed in contact with the end plates of the two adjacent vertebrae via an anterior surgical approach. It is a related objective of the end plate prosthesis of the present invention that the implant procedure not require the use of complex tools to install and position the end plate prostheses in place.

It is an further objective of the present invention that it be implantable in a surgical procedure reducing both the trauma to the patient and the time for the surgeon to

implant the device. It is also an objective of the end plate prosthesis of the present invention that, when installed, it will securely and permanently maintain the integrity and security of the spinal column. It is yet another objective of the end plate prosthesis of the present invention that it promote prompt and permanent ingrowth of bone material intermediate the vertebrae located immediately above and below the removed vertebra to facilitate permanent fusion of the spinal segment. Still further objectives of the end plate prosthesis of the present invention are that it be made of biocompatible material compatible with long term implant in the human body, and that it be either adjustable in length or available in different sizes and configurations to fit a wide variety of patients and different locations in the spine.

The end plate prosthesis of the present invention must be of a construction, which is both durable and long lasting, and it must require no maintenance once it is implanted. In order to enhance the market appeal of the end plate prosthesis of the present invention, it should also be of a simple mechanical design and relatively inexpensive construction to thereby afford it the broadest possible market. Finally, it is also an objective that all of the aforesaid advantages and objectives of the end plate prosthesis of the present invention be achieved without incurring any substantial relative disadvantage.

The aims and advantages are obtained by the following designs and embodiments without any limitation on the protection afforded by the statements of invention above and the claims that follow.

In overview, the implant 200 of the present invention includes, in one embodiment, two end plate discs 202, Figure 2, and vertebral body substitute, prosthesis or implant 206.

Each end plate disc 202 contains holes 208 to allow bone growth across it, and it may be covered with bone growth enhancing material such as hydroxyapetite or Bone Growth Factor. The disc surface 210 that faces the neighboring vertebral body has attachment mechanism such as spikes 212 and/or screws, to provide maximal attachment. The screw would run through the center 214 of the end plate disc into the vertebral body. The screw is inserted by using a 90° screwdriver and passes through the screw hole 214 in the center of the end plate 202. The inner surface of each metal disc 202 is structured to connect and accommodate the vertebral body substitute 206 and to prevent migration of that substitute 202, for example by circumferential pins, knobs or ring. In the Figure 2 embodiment the formation of the holes 208 in the end plates discs 202 is achieved by

pushing the metal down and through which in turn forms upturned standing spikes 216 which are received within the perimeter of the vertebral body substitute 206.

As part of the overall system a variety of different size and/or profiled end plate discs may be provided. This allows different vertebrae in the spine (which are of different sizes) and vertebrae of different individuals (who are of different sizes)to be replace effectively. To assist in quick accurate decision making on the provision of a pair of end plate discs, end plate discs of the same profile and size are provided in the same colour.

In an alternative embodiment the mechanical locking mechanism can be magnetic or electric to attach and lock the vertebral body substitute 206 to the metal discs 202. This mechanism may be changed according to the type of substitute 202 whether it is metal, bone, methylmethacrylate or other.

The end plate disc 202 size may vary according to the vertebral size to be replaced

Existing distractor designs generally function around the use of screws inserted into the vertebrae above and below the site to be worked upon with the spreading of the distractor being conveyed to the vertebrae and hence the entire spinal column by those screws. This causes undesirable levels of intrusion at the site. From the field of spinal disc replacement it is known to use a distractor tool of the type illustrated in Figures 3a, 3b and 3c. In those figures, the very end of the distractor tool 300 is illustrated including the pair of opposing end plates 302 and 304. In the Figure 3a embodiment the distractor tool is shown in its non-distracted form. In this case movement in the direction of arrow A is used to insert the plates 302 and 304 between the vertebrae in a single disc space. The distracting mechanism is then used to transfer the distractor tool 300 to the form illustrated in Figure 3b. This causes the plates 302, 304 to push the vertebrae apart and open up the disc space. Simultaneously with this distraction, the disc replacement 306 can be advanced. In the Figure 3c form, the implant 306 is partially advanced in to the disc space. Throughout the process, however, the plates 302, 304 are present between the surfaces of the implant 306 and the adjacent vertebrae. As a consequence the distraction has to be to a level greater than the size of the disc replacement. Once installed, the tool is withdrawn in the reverse direction so pulling the plates 302, 304 across the top of the implant in the fully distracted configuration and out of the site. Even with this format of tool, therefore, the site has to be distracted further than the size of the implant and the implant has to be maintained in position whilst the distraction plates are pulled back, with a possible risk of disturbing the accurate location of the implant. This would particularly be the case if such a tool was extensively modified to facilitate its use in vertebral body replacement.

The distractor of one embodiment of the present invention 400, shown in Figure 4a, 4b and 4cconsists of two distraction or separation arms 402, 404 that are made to distract the adjacent vertebral bodies through the use of the end plate discs 202. The end plate discs 202 have a specific attachment mechanism to the distractor arm 402, 404, such as screws or holding pins 410, magnetic power or special grooves offer other possibilities, to stabilize and firmly connect the end plate discs 202 to the arms 402, 404. The preferred form, as shown in the illustrations of Figures 4a, b and c, includes the end plate discs 202 in part rest on a section of the upper surface 406 of a pair of fingers 407 extending from the arm 402 and lower surface 408 of a pair of fingers 409 extending from the arm 404. Additionally, lugs 410 present towards the ends of the fingers 407 and 409 cooperate with a recess in the perimeter of the end plate discs 202. This engagement provides a firm mounting for the end plate discs 202 when they are being moved apart to distract the opposing vertebrae. The lugs 410 prevent lateral movement of the end plate discs 202 during the distraction process. As will be described below, however, this engagement mechanism readily allows the distraction tool to be removed once the implant has been installed.

The fingers 407 may be provided with a thinner profile than that shown in Figures 4a, 4b and 4c, this can assist in the handling of the distractor 400 in the incision.

Returning to Figure 4a the distractor 400 is shown in its non-distracted configuration. In this configuration the maximum separation between the point of spikes 412a on one end plate 202 and the spikes 412b on the other end plate 202 is significantly less than the non-distracted space between the vertebral bodies following the corpectomy of the vertebrae being treated. This allows the distractor 400 to be advanced towards the vertebral space and so introduce the end plate discs 202 into that space. The distractor 400 can then be manoeuvred to present the end plate discs 202 to the vertebrae in the desired manner, and at the desired inclination.

The handle 414 on the distractor 400 can then be rotated to cause distraction using the distraction mechanism 416. A wide variety of possible distraction mechanisms exist for increasing the level of distraction in a controlled manner and can be used in the present invention.

During the transition from the Figure 4a configuration to the Figure 4b configuration, the spikes 412 on the end plate discs 202 are brought into contact with the opposing surfaces of the vertebrae and engage therewith by means of the spikes penetrating into the vertebrae. This progresses as the level of distraction progresses.

Continued distraction also causes the vertebrae to be pushed apart by means of the end plate discs 202 thereby increasing the separation between the opposing inner surfaces 418 of the end plate discs 202. This process is advanced until the vertebrae are in the desired position they are to assume after the surgical intervention is completed. This distinguishes the technique of the present invention completely from prior art systems where over distraction is required.

Once in this distracted position a measurement of the separation between the opposing inner surfaces 418 can be taken. The vertebral body substitute 206 can then be cut to the precise desired length from an over length piece of the cylindrical mesh. Once the vertebral body substitute 206 has been obtained in this way it can be moved over the opening 420 between the two end arms of distraction arm 402, Figure 4b. The vertebral body substitute 206 can then be moved down between the arms and into position between the fingers 407 and 409. Following this movement in direction B the vertebral body substitute 206 can be advanced according to directional arrow C into the desired position between the end plate discs 202. Sliding contact between the surfaces 418 of the end plate discs 202 and the points 208 on the vertebral body substitute 206 are possible. Further details of this possibility are described below.

The net result of this process is the position illustrated in Figure 4c wherein the implant is fully assembly, in situ within the spine. The spine details are omitted from this figure for the sake of clarity. The spikes 412 and surfaces of the end plate discs 202 are in contact with the vertebral bodies. Firm contact between the surfaces 418 of the end plate discs 202 and the vertebral body substitute 206 is also occurring.

Given this configuration, illustrated also in the anatomical side view of Figure 5, it is then desirable to remove the distractor 400. To do this the separation between the distractor arms 402 and 404 is reduced, by rotating the handle 414 in the opposite direction, for instance. This has the effect on the ends of the distractor arms illustrated in Figure 7. As can be seen the lugs 410 are removed from the recesses in the perimeter of the end plate discs 202 and the surfaces 406 and 408 disengage from the surfaces 418 of the end plate discs 202 also. The arms 402, 404 and fingers 407, 409 move together down the side of the implant. Once the lugs 410 are clear of the end plate discs 202 the distractor 400 can be removed; taken to the left in Figure 6, to leave the implant in situ. The surgical technique can then be completed in the normal manner leaving the implant in situ in the desired configuration, Figure 7. This process is achieved with minimum distraction to the adjacent vertebrae and without any over distraction of the space.

The arms 402, 404 to end plate disc 202 attachment mechanism may be specific or of variable size according to the diameter of the end plate disc 202.

These arms 402, 404 may for example be connected to each other on the holding side 480, held by the surgeon, and separated on the side 490 connected to the discs 202 or may be connected to a distracting device containing a spreading screw that pushes the arms away from one another.

The spreading device 416 may also be, for example, based on destruction or sliding screw or telescopic spreading device. In addition the spreading device could be facilitated by a special engine (electric or pneumatic or any other type) to apply spreading force on the adjacent vertebrae.

The distractor arms 402, 404 when reaching their endpoint, may have a special measuring device connected to it, which gives the surgeon the exact length of the substitute 206 to be inserted inside. The measurement gauge may provide the length required in metric or imperial measurements, thereby allowing a very accurate vertebral body substitute and hence implant to be prepared to suit the individual spine. All system parts may be made of metal, composite material, polymeric and plastic materials or any other material suitable for this matter.

As a preferred surgical technique, a Formal antero-lateral exposure of the spinal column and corpectomy (removal of the injured vertebra) is done. The vertebral end surfaces of the two adjacent vertebrae facing the corpectomy site, are cleaned up to the burr and bleeding subchondral bone. Templating of the exposed vertebral end plate is done with a special templating device and the proper end plate prosthesis 200 is chosen.

The end plate discs 202 are attached to the distractor arms through the special connecting apparatus and the whole assembly is inserted into the corpectomy site. During insertion, the distance between the distractor arms 402, 404 should be less than the length of the corpectomy size, so its possible to adjust the end plate discs 202 into the burr vertebral end plate.

While the surgeon holds the assembly facing the exposed vertebral end plate, making sure that it dose not migrate posterior into the spinal canal or anterior into the vessels, his assistant detracts the device gradually until the end plates 202 are attached firmly to the burr vertebral end plates facilitated by the penetration of the spikes 212 located on the side of the end plate disc prosthesis.

Once the surgeon feels the distraction process has reached its endpoint level and the end plate prosthesis are strongly attached to the vertebrae, he/she customizes the

vertebral body prosthesis 206 according to the measurement reading on the distraction device 400. At this point he may prefer to insert a screw through the end plate discs 200 into the vertebral body to obtain stronger and solid attachment of the end plate discs 200 to the bone.

Following final trimming of the vertebral body substitute 206, the surgeon slides the vertebral body substitute along the distractor arms 402, 404 into the corpectomy site until it reaches the final location, resting between the metal end plate discs 200 and locked into them.

At this point the distraction device arms 402, 404 are approximated to each other detaching from the end plate disc 202 and removed form the operating field.

Various embodiments of the invention or variations on the theme set out above are possible. For instance the cylindrical mesh style cage described above could be replaced by cages of different cross-sectional profiles. It would also be possible to replace the mesh style vertebral substitute body 206 detailed above with a two part substitute which is inserted in a first reduced configuration and then expanded to an enlarged configuration, the ends of the vertebral substitute body contacting the end plate discs 202 in the expanded configuration. Expansion could be achieved by rotating one threaded component relative to another component with which it is threadably engaged so as to increase the separation between the end surfaces of such a vertebral body substitute. Screw threads, cam style surfaces or other such routes could be used to achieve the variation.

It is possible to bring the vertebral substitute body 206 into position by slightly over-distracting the end plate discs 202. This allows the end of the vertebral substitute body 206 to pass over, the pins, knobs or ring structure which are used to retain the vertebral substitute body 206 in position relative to the end plate discs 202 in use. The extent of over-distraction required is quite minimal compared with prior art, and can be reduced or even eliminated by the careful design of the retention system used to maintain the position between the vertebral substitute body 206 and the end plate discs 202.

As shown in Figure 8 it is possible to configure the protrusion 802 at a lower height compared with the surface 804 of the end plate disc 202 compared with other protrusions 806 and 808. In this way, if the protrusion 802 is on the side of the end plate disc 202 closest to the distractor 400 during deployment then that is the only protrusion that has to be crossed by the vertebral substitute body 206 and as a consequent the degree

of over distraction is minimalised compared with the degree which would be necessary to overcome the protrusion height 806, 808.

It is also possible to configure one or more of the protrusions and the end of the vertebral body substitute 206 so that the vertebral body substitution 206 can slide passed the protrusion when being inserted, but cannot move back during use due to a change in configuration which occurs after the vertebral body substitute 206 is in the correct position. In the Figure 8 style embodiment this could be achieved for instance by making the protrusion 802 match the profile of the aperture 810 which allows it to pass over it and match the corresponding aperture on the other side of the vertebral substitute body 206 which has to pass over the protrusion 802 first. A triangular shaped protrusion of the relevant height, therefore, might be used.

The changing configuration after the vertebral body 206 is in position could be achieved by moving the protrusion 802, for instance by bending it upwards, generating a protrusion, for instance by inserting a component or by bending the protrusion up from the plane of the end plate disc 202 into position. Alternatively, or in combination with such techniques, the vertebral body substitute 206 could be rotated so that the protrusion 802 no longer aligns with the apertures in the end of the vertebral body substitute 206 which it is designed to pass through. Thus some of the apertures might have a different configuration from others or apertures might only be present in limited parts of the end of the vertebral body substitute 206. It would also be possible to use memory metal effects to potentially introduce the vertebral substitute body 206 in a first configuration where it can slide between the protrusions 802, 806 or other retention mechanism, but which on exposure to the body's temperature reverts to another configuration in which it cannot pass these protrusions simply by virtue of a sliding motion. In these various situations and others the vertebral body substitute 206 can be introduced into the desired position and firmly retained in location once there without having to over distract the vertebrae at all.

The implants, techniques and concepts described above can be used to replace more than one vertebrae at once, with a pair of end plate discs and a vertebral body substitute being used to replace one, two, three or potentially even more vertebrae.

Whilst the invention has been described above primarily in relation to a disc style end plate, other configurations are possible. For instance a ring structure which a substantial central aperture could be used. The ring structure might have a number of spokes on its outer edge which could pass between and engage with the apertures in the

end of the vertebral substitute body, for instance the half diamond gaps illustrated in Figure 8.

The vertebral body substitute is preferably hollow and filled with material which promotes the desired fusion of the vertebrae. The material may be allograft, cement or other such materials.

The system is described above in relation to a vertebrae body replacement, but is also of use in achieving vertebral replacement. In such a case the system is used in a similar way, but the distraction process is performed on adjacent vertebrae rather than vertebrae which are separated by one or more vertebrae prior to the corpectomy. The disc to be replaced is removed using normal surgical procedure. To achieve the desired degree of distration, but no more, the distractor is inserted in the type of configuration shown in Figure 4a with the ends of the pairs of fingers close together. The ends of the fingers support a disc component in each case. The disc component is used in the same way as the end plate discs described above. The disc component is inserted into the disc space and the distractor is then expanded to bring the disc component into contact with the opposing surfaces of the two vertebrae. Continued distraction expands the disc space to the desired level. The body of the disc replacement is then inserted. The distractor can then be relaxed to leave the disc components and body in contact with one another. The implant is thus formed in-situ once again.

CLAIMS:

1. A spinal part replacement, the replacement including a first component, a second component and a body, at least a part of the body being provided between the first component and the second component in the assembled form, the first and second components being introduced to the location of the spinal part to be replaced separately from the body.

2. A sprinal part replacement, preferably according to claim 1, in which the replacement including a first component a second component and a body, the first component engaging one end of the body, the second component engaging the other end of the body.

3. A replacement according to claim 1 or claim 2 in which one or more spikes and/or points and/or protrusions are provided on one or both faces of the first component.

4. A replacement according to any preceding claim in which one or more spikes and/or points and/or protrusions are provided on one face of the first component to assist the engagement between the first component and the adjacent vertebra in use.

5. A replacement according to any preceding claim in which one or more spikes and/or points and/or protrusions and/or rings are provided on the face of the first component with which the body engages in use.

6. A replacement according to any preceding claim in which the first component is provided with one or more engagement locations, an instrument engaging with the engagement locations during introduction of the first component to the location in use.

7. A replacement according to any preceding claim in which the first component is provided with an aperture, preferably in its centre, for receiving a screw or other releasable fastener.

8. A replacement according to any preceding claim in which the second component has any of the features set out in any of claims 1 to 7.

9. A replacement according to any preceding claim in which the body has a first end which engages with the body, ideally due to a match between the profile of a least a part of the body and at least a part of the first component and the body has a second end which engages with the body, preferbaly due to a match between the profile of at least a part of the body and the second component.

10. A replacement according to any preceding claim in which the body is a cage.

11. A replacement according to any preceding claim in which one or more parts of the body cooperates with one or more parts of the first component and/or second component to resist separation of the first component from the body and/or second component from the body.

12. A replacement according to any preceding claim in which the body is slid into position over a surface of the first and/or second components.

13. A replacement according to any preceding claim in which the body can slid into position in one orientation of the body relative to the first component and/or the second component and the body cannot slid relative to the first component and/or second component in one or more other orientations.

14. A replacement according to any preceding claim in which an end of the body engages the first component without passing into or through it, and another end of the body engages the second component without passing into or through it.

15. A system for use in providing a spinal part replacement, the system including one or more spinal part replacements, a spinal replacement including a first component, a second component and a body, at least a part of the body being provided between the first component and the second component in the assembled form, the first and second components being introduced to the location of the spinal part to be replaced separately from the body, the system further providing a distractor instrument.

16. A system for use in providing a spinal part replacement, the system including one or more spinal part replacements, a spinal part replacement including a first component a

second component and a body, the first component engaging one end of the body, the second component engaging the other end of the body, the system further providing a distractor instrument.

17. A distractor instrument, the distractor instrument having an end inserted in a surgical location and an end held by a user, the inserted end having one or more engagement locations to support a first component and one or more engagement locations to support a second component, the first and second components not being a part of the instrument, the separation of the engagement locations for the first component and engagement locations for the second component being variable.

18. A system according to claim 16 or claim 17 or an intrument according to claim 17 in which the location end of the instrument includes a first engagement location between the instrument and a first component and the location end of the instrument includes a second engagement location between the instrument and the second component.

19. An instrument according to claim 18 in which the engagement location is provided, in one or both cases, on a projection from the body of the instrument, the projection being in the form of two elements with a gap between them.

20. An instrument according to any of claims 16 to 19 in which the engagement location includes a first part or point which engages a surface of the first component or second component.

21. An instrument according to any of claims 16 to 20 in which points of engagement, preferably in addition to the points of engagement of claim 20, are provided which engage with the side of the first component and/or second component.

22. An instrument according to any of claims 16 to 21 in which the instrument provides a readable measure of the extent of distraction and the measure is of the distance between the two opposing faces of the first and second components.

23. An instrument according to any of claims 16 to 22 in which the extent of distraction/separation of the engament locations with the first and second components is

variable between a first state and a second state, the first state represents a lower extent of distraction/separation than the second state.

24. A method of providing a spinal part replacement, the method including:-

removing the part of the spine to be replaced by means of an incision;

providing a spinal part replacement including a first component, second component and body;

mounting the first and second components on a distraction instrument;

inserting the first and second components and a part of the distraction instrument into the space left by the part of the spine which has been removed;

increasing the spacing between the first component and the part of the distraction instrument the first component is mounted upon relative to and the second component and the part of the distraction instrument the second component is mounted upon, the first component contacting one vertebra, the second component contacting an adjacent vertebra;

increasing the spacing between the first component and the second component further, the first and second components increasing the spacing between the one vertebra and the adjacent vertebra;

inserting the body between the first component and the second component;

reducing the separation between the part of the distraction instrument the first component was mounted on and the part of the distraction instrument the second component was mounted upon;

removing the distraction instrument from the incision.

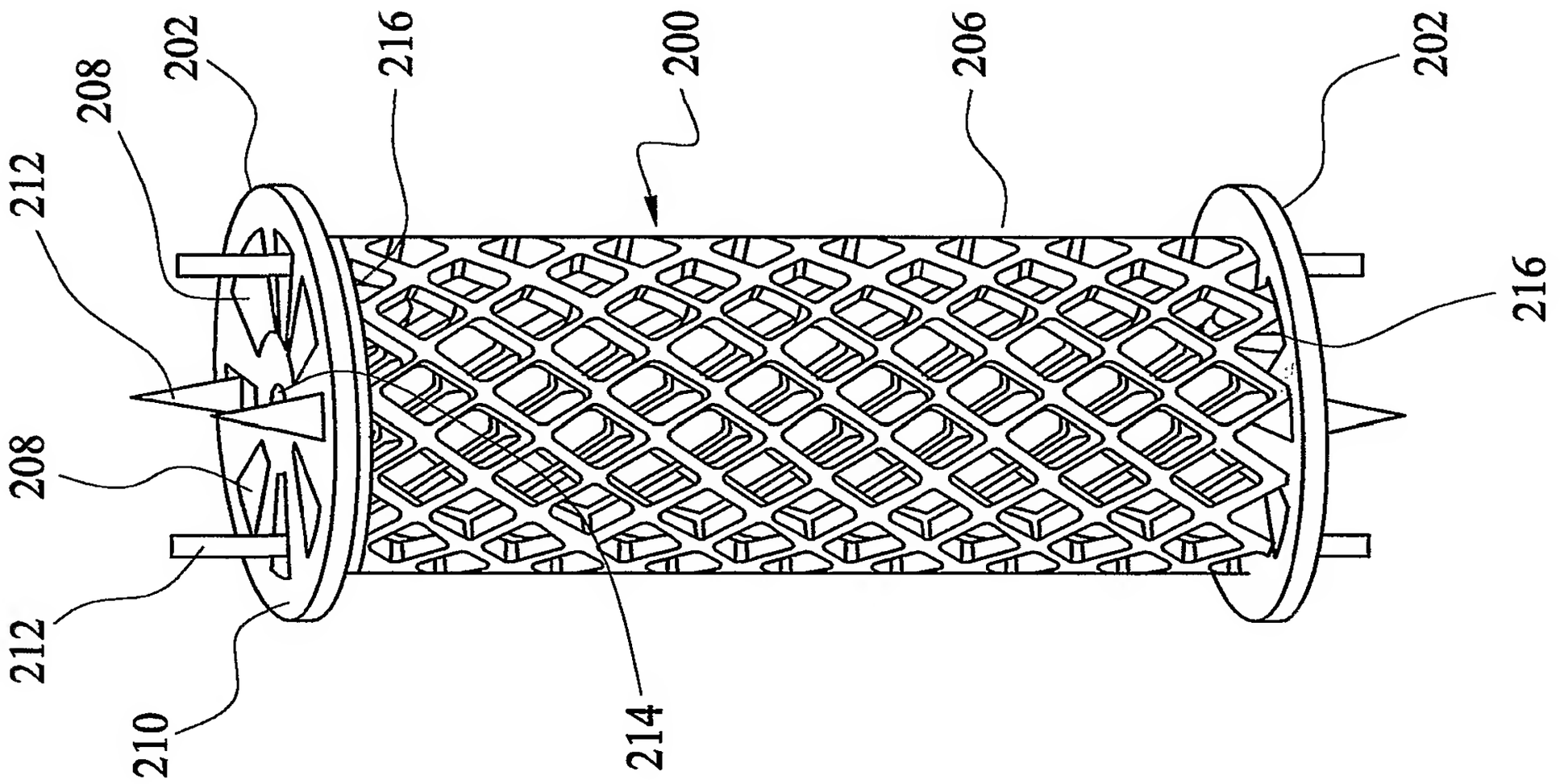


FIG. 2

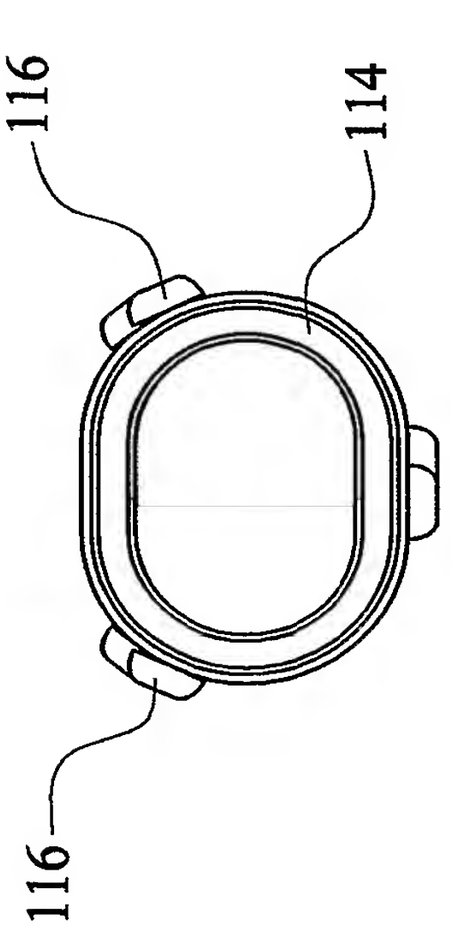


FIG. 1a - Prior Art

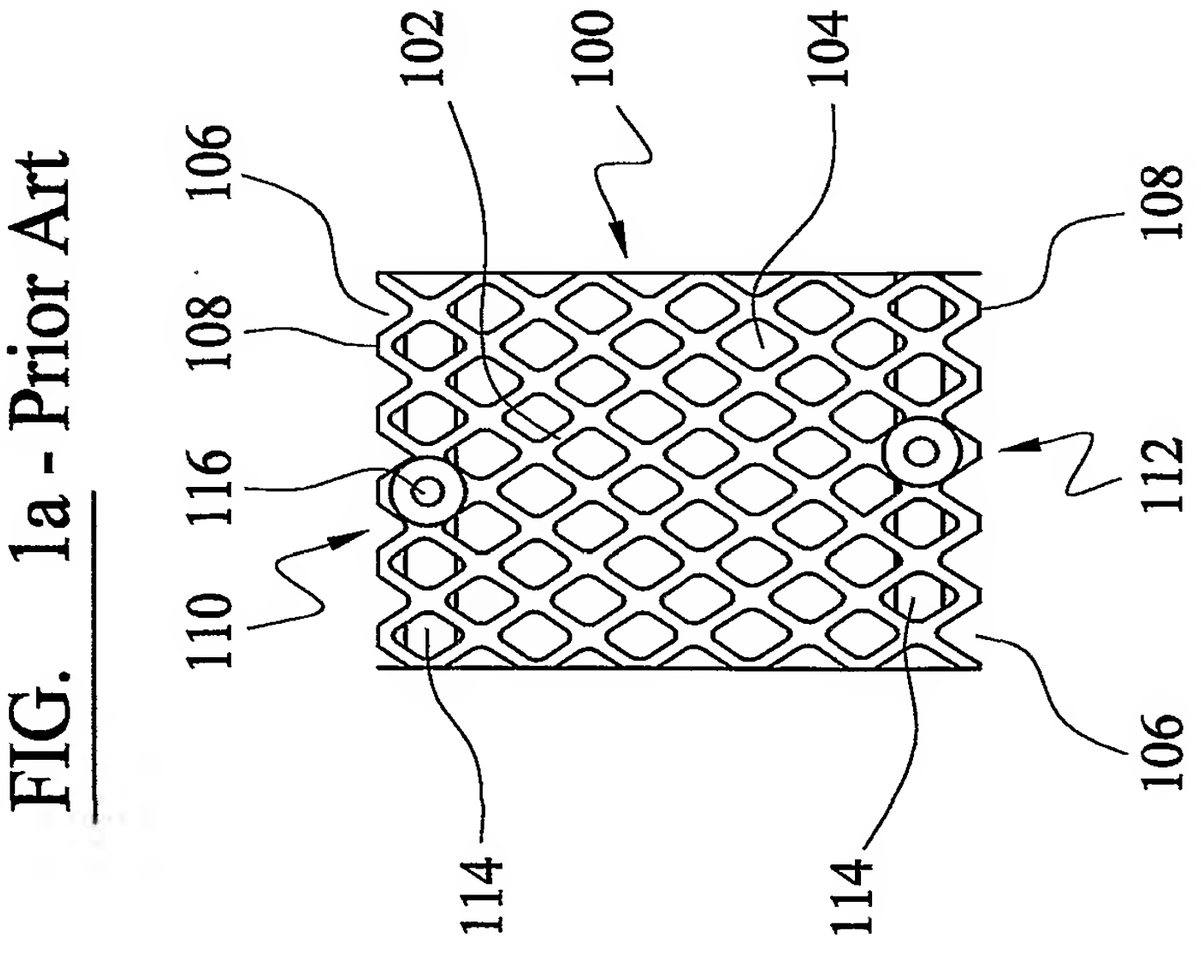


FIG. 1b - Prior Art

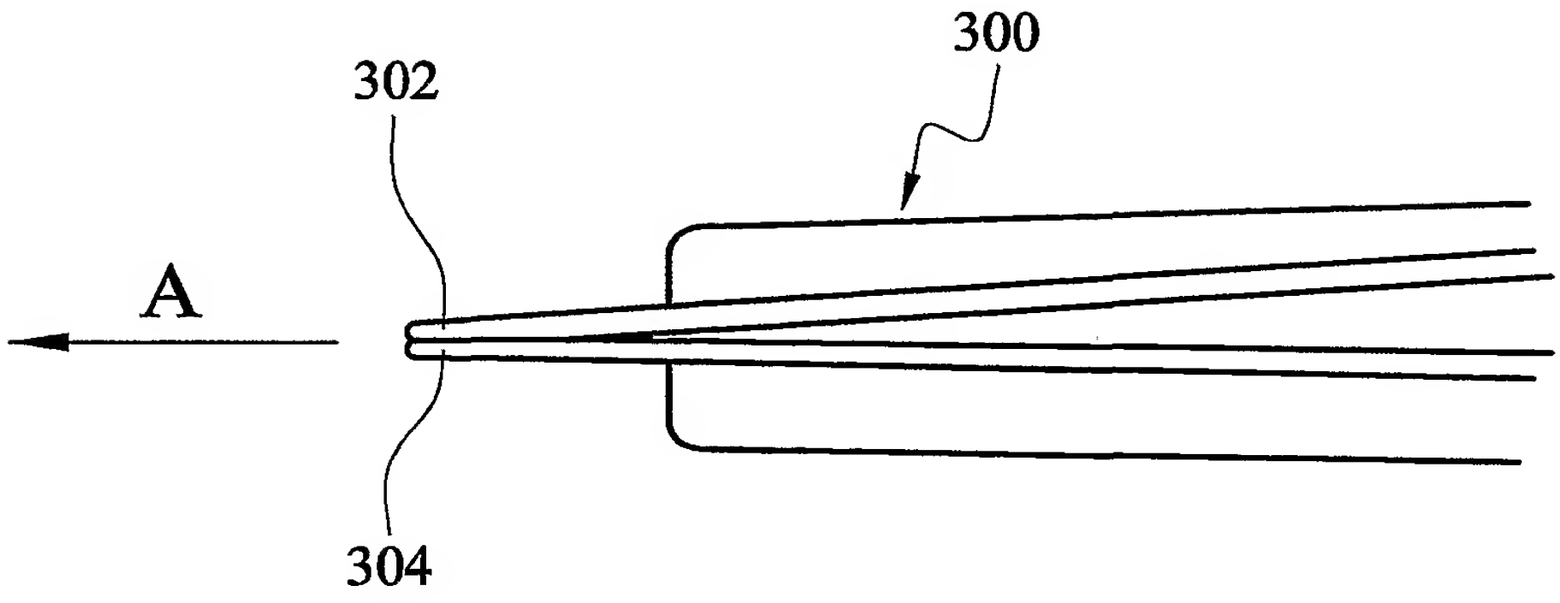


FIG. 3a - Prior Art

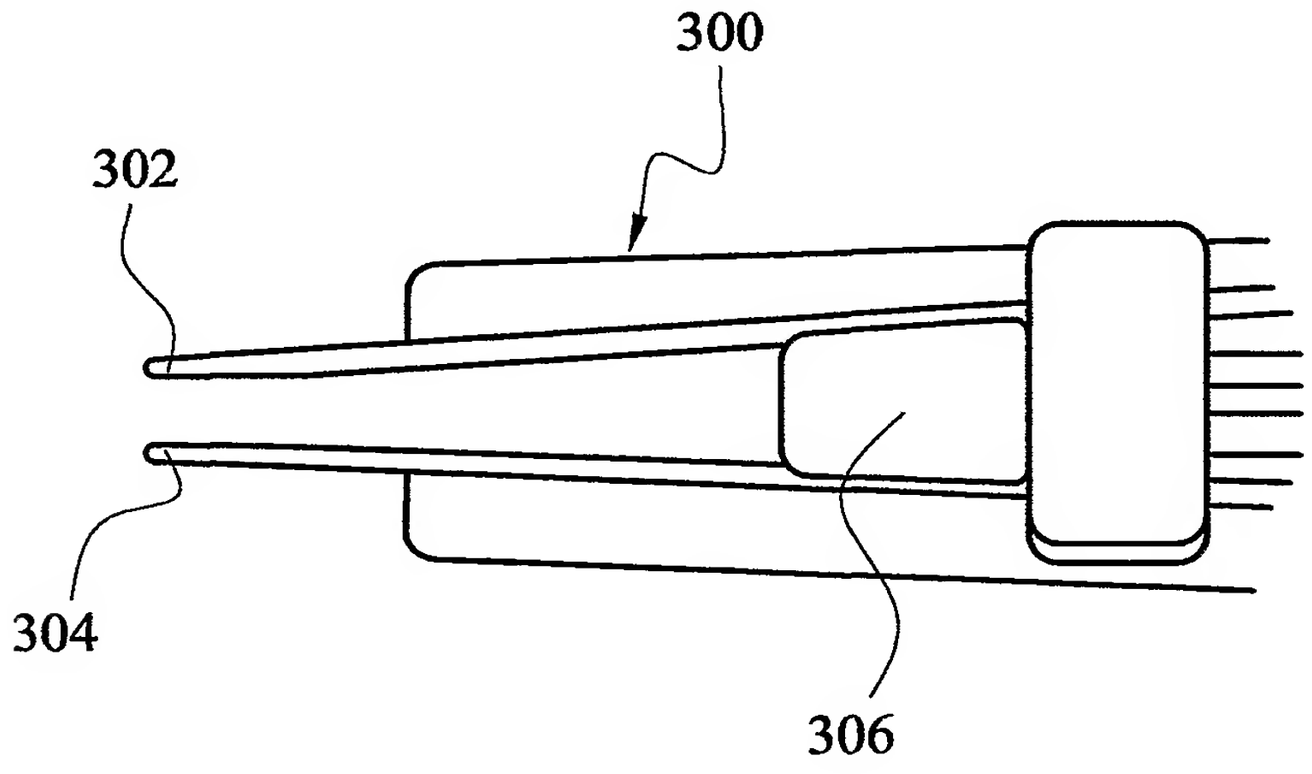


FIG. 3b - Prior Art

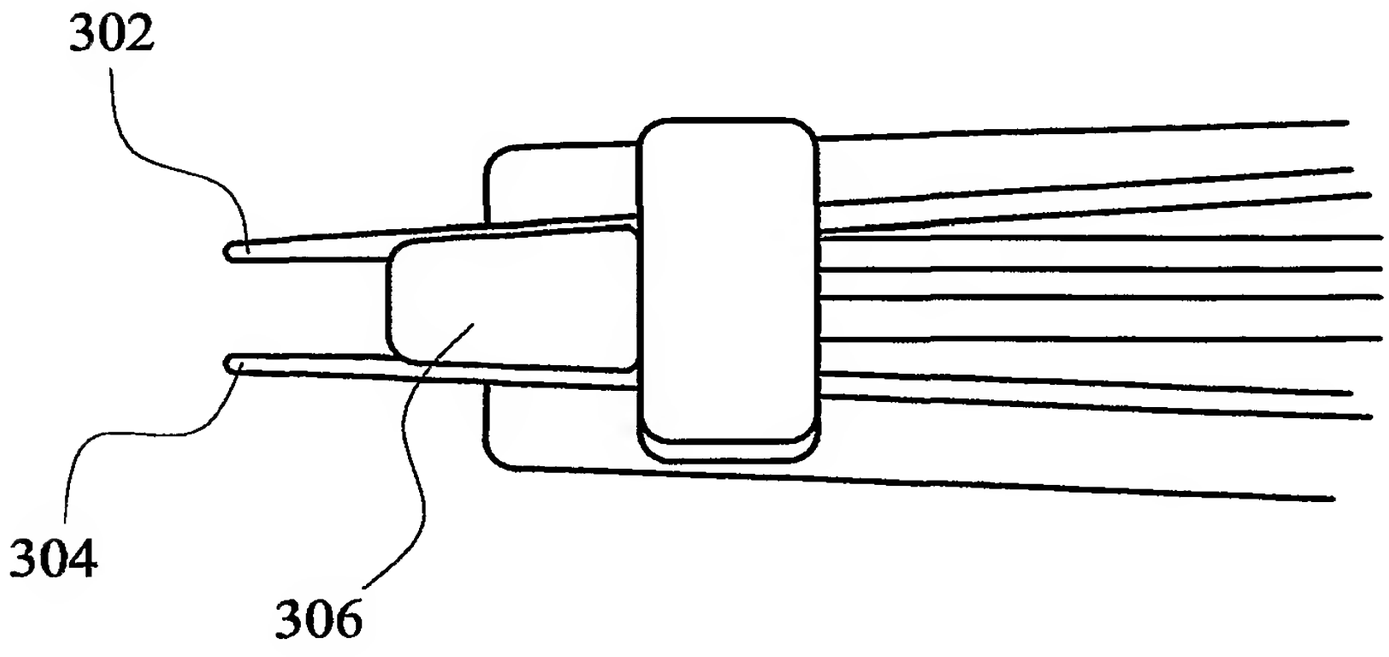
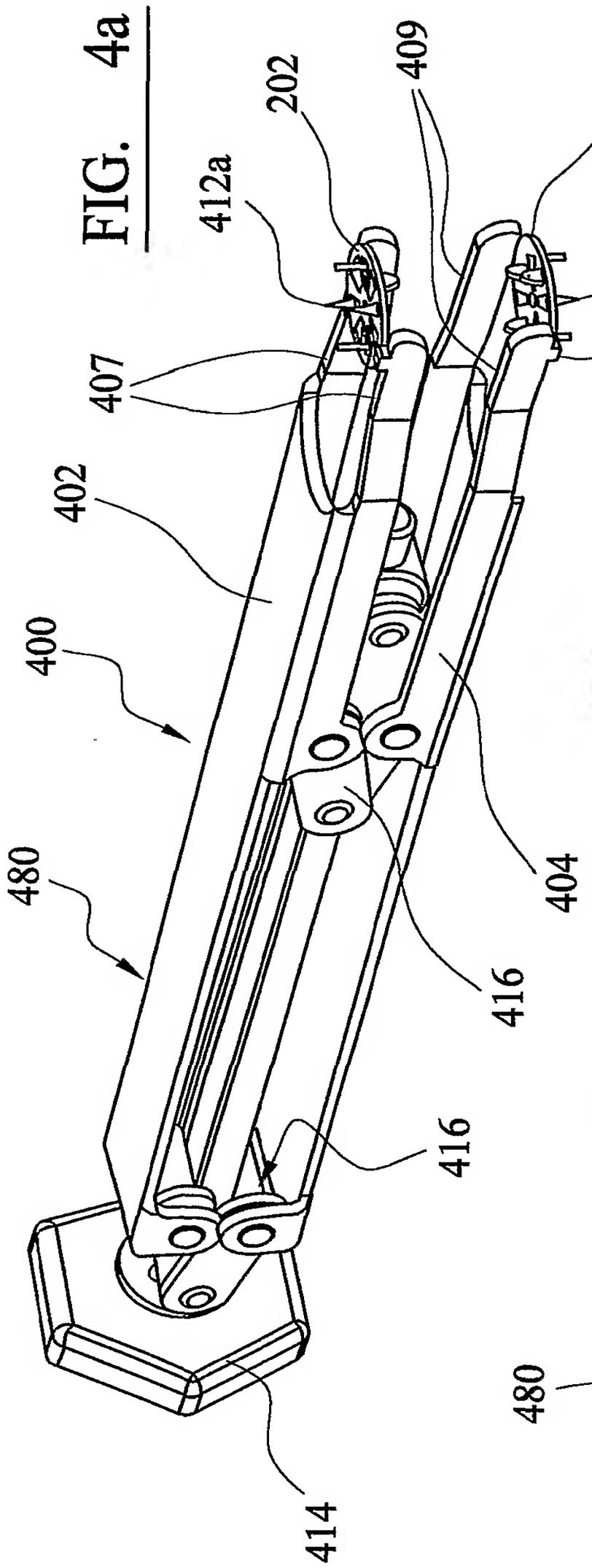


FIG. 3c - Prior Art

FIG. 4a


412a
202
409
202
412b
410
407
402
400
480
404
416
416
414

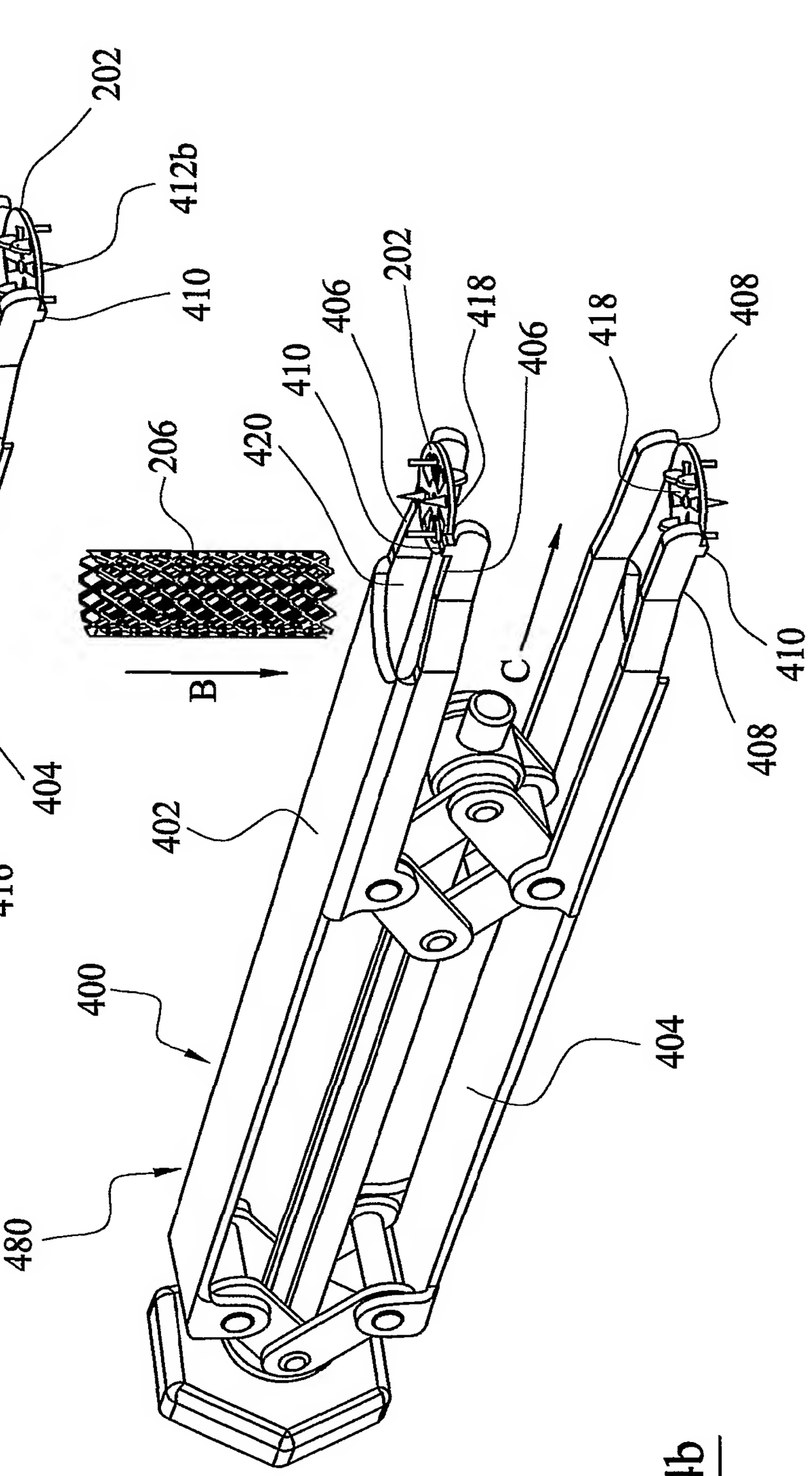

202
406
410
418
406
418
408
206
420
B
C
410
408
402
400
404
480

FIG. 4b

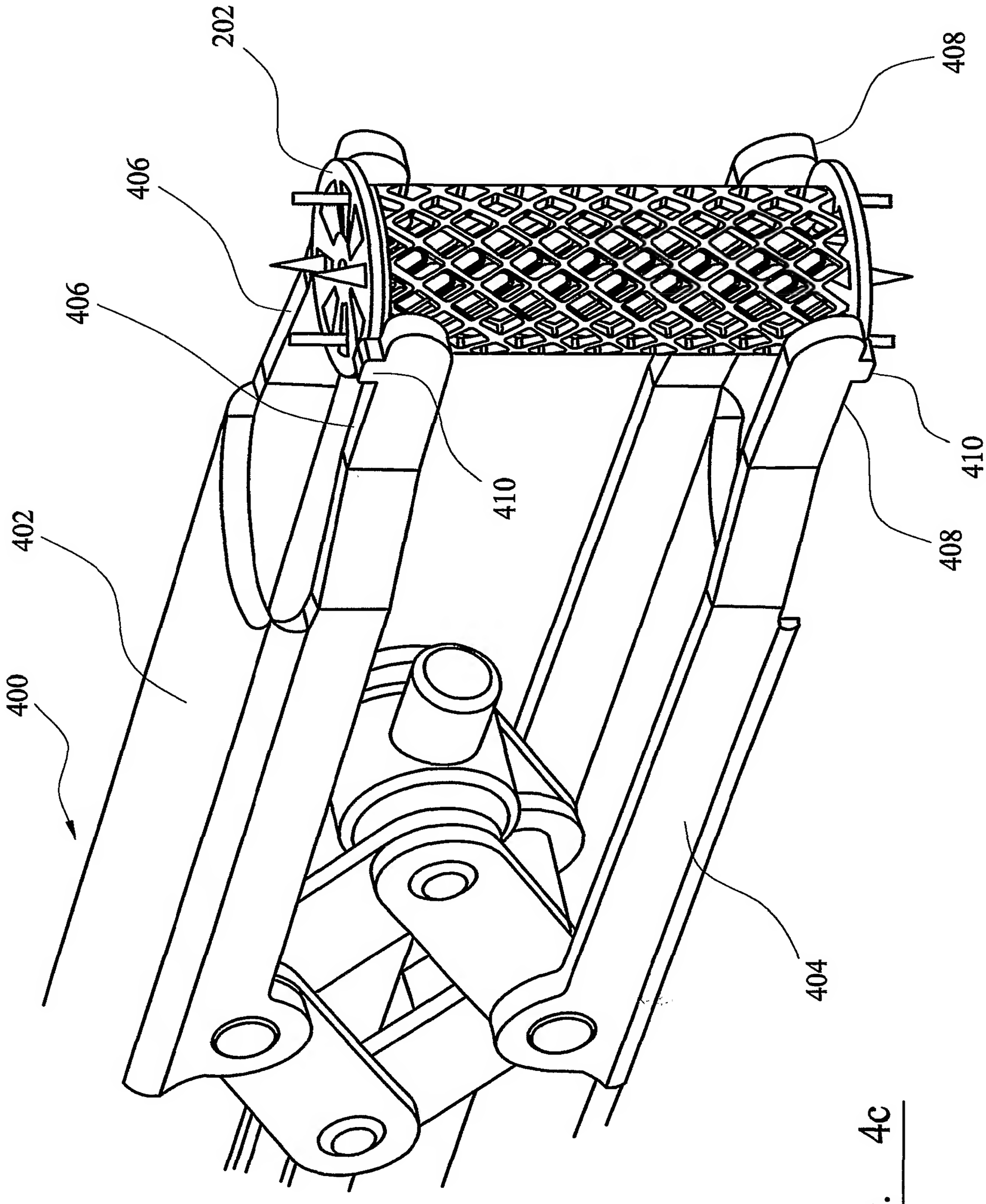


FIG. 4c

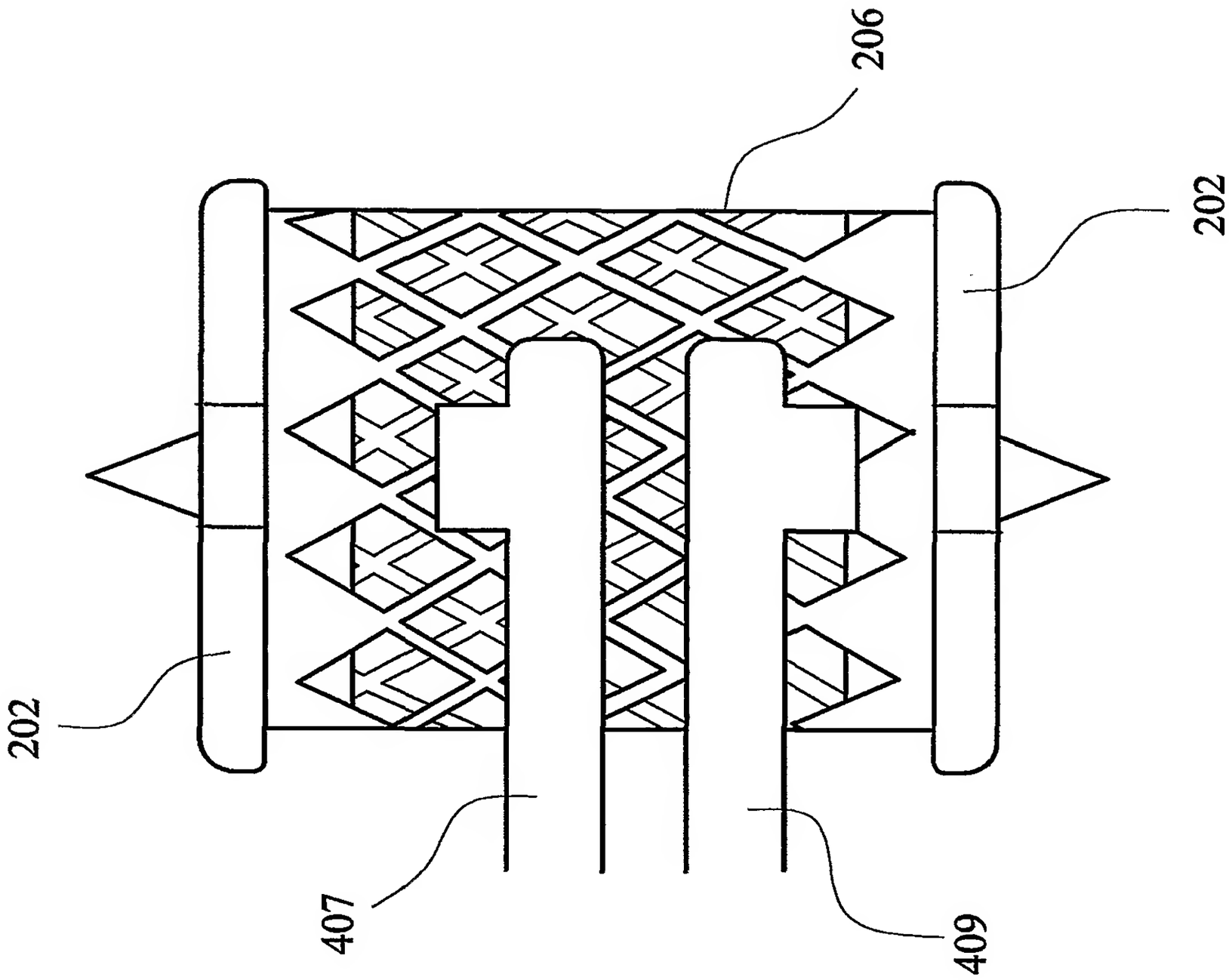


FIG. 6

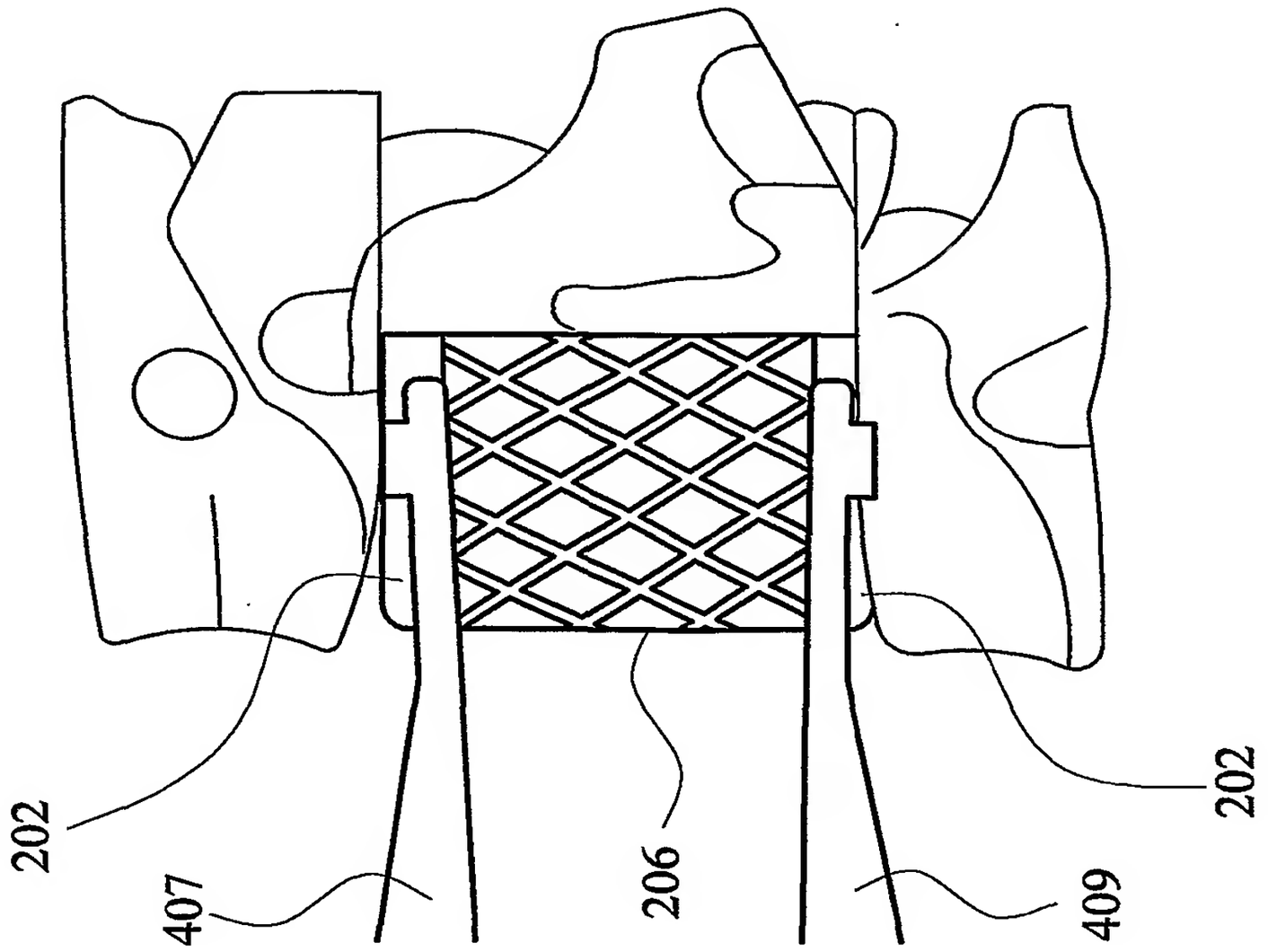


FIG. 5

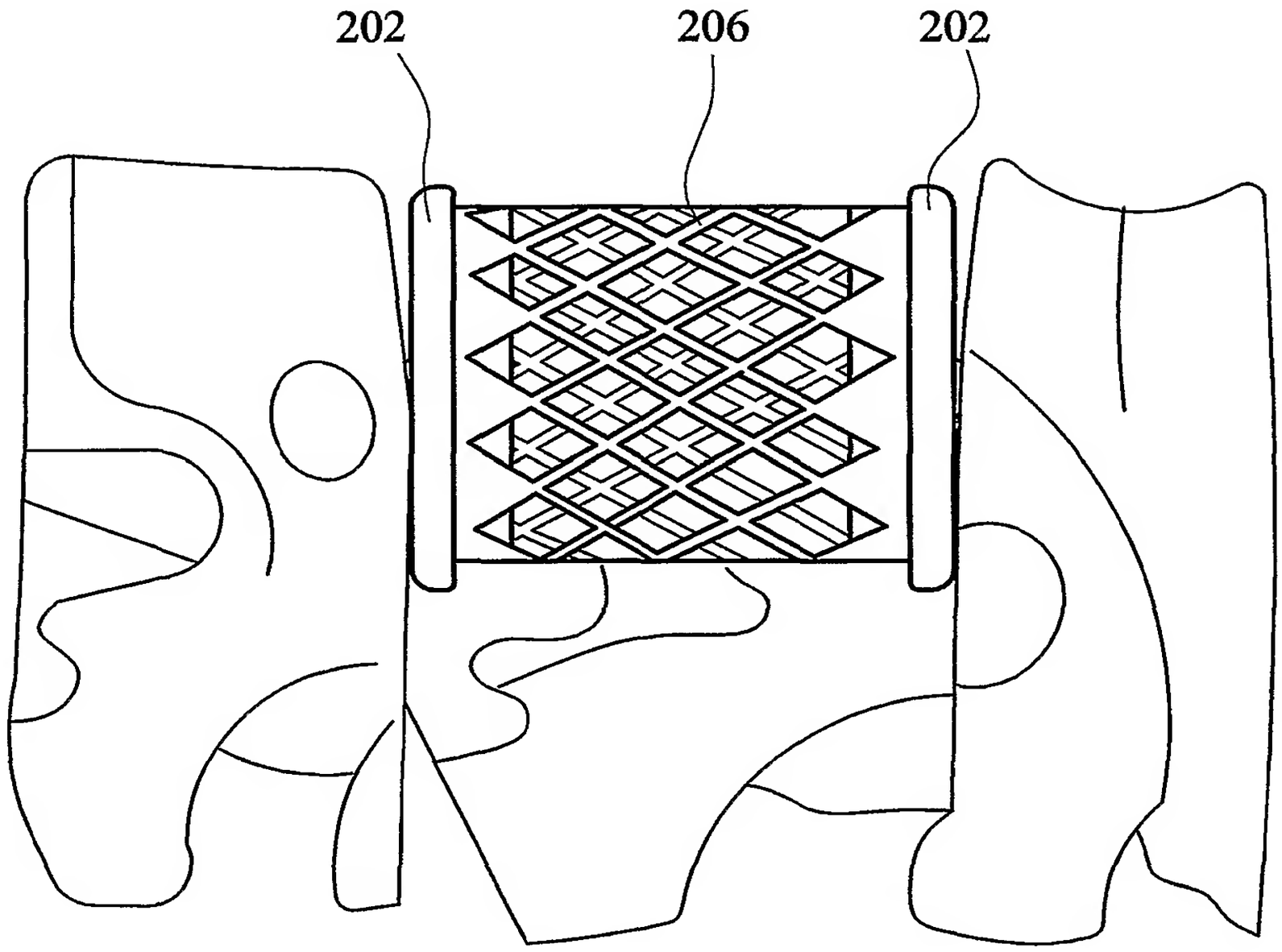


FIG. 7

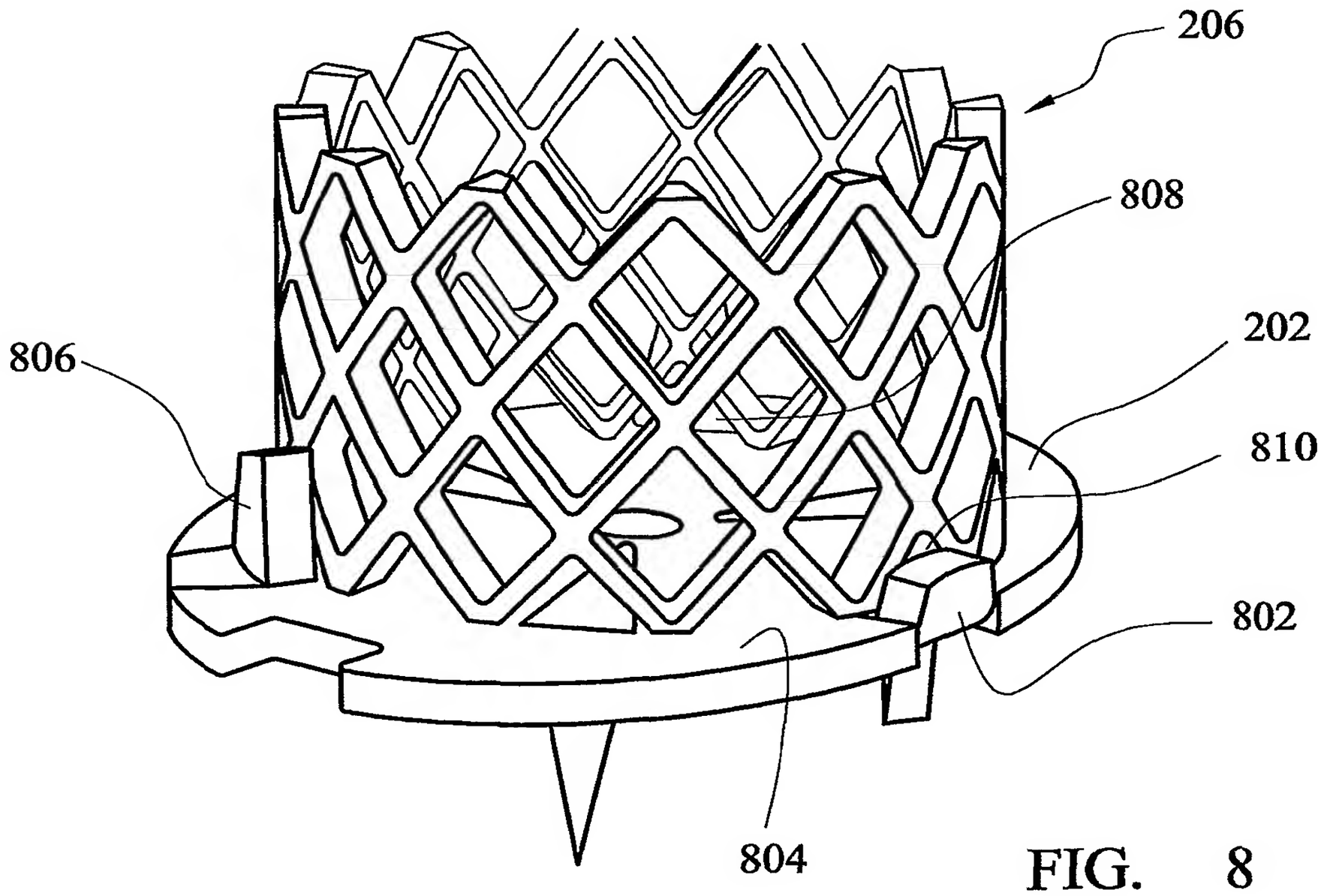


FIG. 8